Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative evaluation of effects of adding Dexmedetomidine, Dexamethasone and Na Bicarbonate to Ropivacaine in ultrasound-guided supraclavicular block on the quality of the block in orthopedic surgery

Protocol summary

Study aim
Determining the effect of adding dexmedetomidine, dexamethasone, and sodium bicarbonate to ropivacaine in the ultrasound-guided supraclavicular block on the quality of the block in orthopedic surgery

Design
A clinical trial with the control group, parallel groups, three-way blind, randomized, phase 3 on 120 patients. Random Allocation software was used for randomization.

Settings and conduct
Patients are placed in a semi-sitting position (30 degrees), then the supraclavicular block is performed by an ultrasound guide and half of the drug is injected in the pocket corner and the other half in the middle of the brachial plexus. All injections are performed using a spinal needle No. 22 connected to the Extension tube. The drug used for the block is prepared and coded by the project partner as follows and is provided to the executor. The codes are provided to the executor after sampling and statistical analysis.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 years and older Weight (Lean body mass) between 50 to 90 kg ASA 1 and 2 were Introduced for upper limb surgery (distal to the lower third of the arm) Exclusion criteria: Local infection at the site of the block Existence of coagulation disorder or taking anticoagulants Hypersensitivity to dexmedetomidine, dexamethasone, and ropivacaine

Intervention groups
In all patients, the supraclavicular block is performed under ultrasound guide by injection of 30 ml of ropivacaine 5 mg/ml by the performer. In the first to third groups, the following items are added in a volume of one ml, respectively: 30 micrograms of dexmedetomidine, 0.6 ml of 7.5% bicarbonate solution, 4 mg (1 ml) of dexamethasone In the control group, 1 ml of normal saline is added to the drug.

Main outcome variables
Interval of drug injection to the onset of sensory and motor block, duration of sensory and motor block

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140129016415N9**
Registration date: **2022-06-26, 1401/04/05**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-26, 1401/04/05**
Update count: **0**

Registration date
2022-06-26, 1401/04/05

Registrant information

Name
Mohammad Golparvar
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 3220 1750
Email address
golparvar@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-05, 1401/03/15

Expected recruitment end date
2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of effects of adding Dexmedetomidine, Dexamethasone and Na Bicarbonate to Ropivacaine in ultrasound-guided supraclavicular block on the quality of the block in orthopedic surgery

Public title

Evaluation of effects of adding Dexmedetomidine, Dexamethasone and Na Bicarbonate to Ropivacaine in ultrasound-guided supraclavicular block

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 years and older Weight (Lean body mass) between 50 to 90 kg ASA 1 and 2 Introduced for upper limb surgery (distal to the lower third of arm)

Exclusion criteria:

Local infection at the site of the block Existence of coagulation disorder or taking anticoagulants Hypersensitivity to dexmedetomidine, dexamethasone and ropivacaine

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are placed in one of four experimental groups using a table of random numbers. The default movement in the table from right to left and from bottom to top is considered and the numbers 0 to 29 in group 1 and the numbers 30 to 59 in group 2 and the numbers 60 to 89 in group 3 and the numbers 90 to 119 They are in group 4. The starting point of the movement in the table is determined randomly by the first client by placing a finger with his eyes closed on the table.

Blinding (investigator's opinion)

Double blinded

Blinding description

The project partner prepared the drug used to perform supraclavicular block by adding additive (dexmedetomidine, sodium bicarbonate, dexamethasone, or normal saline) to ropivacaine in similar syringes and in the same final volume and after coding (1 to 4) It is provided to the executor, the executor (drug injector and data collector) and the patient are not aware of the type of drug added to the injectable ropivacaine and the codes will be opened after sampling and statistical analysis are completed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

No.100, Jahan-nama valley, Babalrahmeh street, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

8136656433

Approval date

2022-04-12, 1401/01/23

Ethics committee reference number

IR.MUI.MED.REC.1401.019

Health conditions studied

1

Description of health condition studied

upper limb surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The interval between the injection of the drug and the onset of anesthesia and immobility

Timepoint

Every 3 minutes

Method of measurement

Evaluation of the movement block is done using 2 movement examinations: 1- Asking the patient to place the index and middle fingers against each other while the other fingers are in the extension position 2- Maintaining the forearm position in a 90 degree position

with the arm in a position The performer places the patient's arm perpendicular to the patient's body. The sensory block is evaluated by pressing the Blunted needle on the three points of the dorsal hand, forearm and arm.

Secondary outcomes

1

Description
Duration of sensory and motor block
Timepoint
Every 15 minutes
Method of measurement
Evaluation of the movement block is done using 2 movement examinations: 1- Asking the patient to place the index and middle fingers against each other while the other fingers are in the extension position 2- Maintaining the forearm position in a 90 degree position with the arm in a position The performer places the patient's arm perpendicular to the patient's body. The sensory block is evaluated by pressing the Blunted needle on the three points of the dorsal hand, forearm and arm.

Intervention groups

1

Description
First intervention group: 30 micrograms of dexmedetomidine in 1 ml of normal saline is added to the 30 ml of ropivacaine used to block.
Category
Treatment - Drugs

2

Description
Second intervention group: 0.6 ml of 7.5% bicarbonate solution is increased to 1 ml with normal saline and then added to Block drug (30 CC ropivacaine)
Category
Treatment - Drugs

3

Description
Third intervention group: 4 mg (1 ml) of dexamethasone is added to the 30 ml of ropivacaine used to block.
Category
Treatment - Drugs

4

Description
Control group: 1 ml of normal saline is added to 30 ml of ropivacaine used to block.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
Mohammad Golparvar
Street address
No.100, Jahan nama valley, Babalrahmeh street, Isfahn, Iran
City
Isfahan
Province
Isfehan
Postal code
8136656433
Phone
+98 31 3220 1750
Email
golparvar@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Mansoor Siavash
Street address
No.4 Headquarters building, Isfahan university of Medical Sciences, hezarjarib Street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 8138
Email
research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mohammad Golparvar

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
No.100, Jahan nama valley, Babalrahmeh street, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
8136656433

Phone
+98 31 3220 1750

Email
golparvar@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mohammad Golparvar

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
No.100, Jahan nama valley, Babalrahmeh street, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
8136656433

Phone
+98 31 3220 1750

Email
golparvar@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mohammad Golparvar

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
No.100, Jahan nama valley, Babalrahmeh street, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
8136656433

Phone
+98 31 3220 1750

Email
golparvar@med.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available